IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel.* ZACHARY SILBERSHER, *Plaintiffs*, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED, *Defendants*.	Civil Action No.: 19-12107 (KM)(JBC) Motion Date: November 4, 2019 *Document electronically filed*

PLAINTIFF-RELATOR ZACHARY SILBERSHER'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS (DKT. 79)

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INTRODUCTION

The Second Amended Complaint (Dkt. 63) ("Complaint") alleges that Defendants[1] committed fraud to cause the United States and Plaintiff States to pay substantially more for the prostate cancer drug Zytiga® (abiraterone acetate) than they should have.

Specifically, Defendants misled the United States Patent and Trademark Office ("Patent Office") into issuing an invalid follow-on patent—U.S. Patent 8,822,438 ("the '438 patent")—after Zytiga's initial patent period expired. It is beyond dispute that the '438 patent is invalid and should not have been granted. This Court, the Patent Trial and Appeal Board ("PTAB"), and the Federal Circuit all found as much. *See generally BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063, 1076 (Fed. Cir. 2019). Indeed, the Patent Office had rejected the patent application multiple times because the claimed invention (co-administering abiraterone with prednisone) was obvious. To overcome the Patent Office's objections, Defendants falsely represented that "secondary considerations" overcame obviousness. In particular, they falsely represented that Zytiga's commercial success was attributable to the invention claimed in the '438 patent, and that Zytiga performed well against its competitors in key markets. But for that fraud, the patent would not have issued, and Zytiga would have faced generic competition starting in December 2016. Because of the fraud, however, Defendants extended their monopoly, barring generic competitors.

The Complaint goes further, alleging that Defendants never expected the '438 patent to survive scrutiny in litigation or *inter partes* review ("IPR"). Defendants nevertheless sought the patent, and lied to get it, because they knew they could manipulate the regulatory structure by listing the '438 patent in the Food and Drug Administration's ("FDA") Orange Book, which would delay generic alternatives to Zytiga for at least 30 months. During that period and

[1] Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC (together, "Janssen"); Johnson & Johnson (Janssen together with Johnson & Johnson, "J&J"); and BTG International Limited ("BTG") (J&J and BTG collectively, "Defendants").

afterwards, Defendants continued charging inflated monopoly prices to all payors, and particularly the government, whose programs cover 80% of all prostate cancer patients. Defendants knew the high prices they were charging for Zytiga were only possible because they deceptively obtained an invalid patent. As a direct and intended result of Defendants' fraud, government payors have paid hundreds of millions more for Zytiga than they should have.

If those allegations are true, Defendants are liable under the False Claims Act ("FCA"). The FCA imposes liability on any person who "presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). A "claim" is "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property," that is presented to the government. § 3729(b)(2)(A). A falsity is material if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." § 3729(b)(4). No "specific intent to defraud" is required; it is enough that the defendant acts with actual knowledge, deliberate ignorance, or reckless disregard of the truth. § 3729(b)(1).

As this capacious statutory language suggests, the FCA is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968); *United States* ex rel. *Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1170-71 (9th Cir. 2006). The statute is construed "broadly." *See, e.g., United States* ex rel. *Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017). Importantly here, false statements create liability even if they are not made directly to government payors, so long as the statement is "integral to a causal chain leading to payment." *United States* ex rel. *Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005); *United States* ex rel. *Krahling v. Merck & Co.*, 44 F. Supp. 3d 581, 608 (E.D. Pa. 2014). And in cases, like this one, involving inflated drug

pricing, fraud is material if it tends to cause the defendant to receive "more money than it should have gotten." *United States* ex rel. *Garbe v. Kmart Corp.*, 824 F.3d 632, 639 (7th Cir. 2016).

Using fraud to cause the government to overpay for goods is a heartland FCA violation. For example, if a defendant reported inaccurate market prices to the government to inflate the price the government would pay for drugs, the FCA would impose liability for the subsequent claims. *See, e.g., Garbe*, 824 F.3d at 639; *United States* ex rel. *Streck v. Bristol-Myers Squibb Co.*, 2018 WL 6300578, at *9 (E.D. Pa. Nov. 29, 2018), *clarified on denial of reconsideration*, 370 F. Supp. 3d 491 (E.D. Pa. 2019); *see also Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 183 (3d Cir. 2001) (explaining that the FCA was enacted, in part, because the government had been "charged exorbitant prices for goods delivered") (quotation marks omitted); *United States* ex rel. *Hayes v. CMC Elecs., Inc.*, 297 F. Supp. 2d 734, 736 (D.N.J. 2003). The fact that Defendants here *manipulated* the market price through an upstream fraud—instead of merely *misreporting* it—does not make their conduct less culpable, or the statute less applicable. If anything, Defendants' conduct here is worse than frauds already found actionable under the FCA.

The bottom line is simple: The Complaint shows that Defendants' fraud caused the government to pay overcharges for Zytiga exceeding hundreds of millions of dollars. This is a cognizable FCA violation—and certainly enough to survive the pleading stage. *See infra* §§ I-III. Defendants' affirmative public disclosure bar defense, by contrast, lacks merit. *See infra* § V.

BACKGROUND

For purposes of this motion, the Court should treat the following facts as true.

First, the '438 patent, which claims the "invention" of co-administering abiraterone in combination with prednisone (Complaint, ¶ 68), is invalid because it was obvious. The patent was obvious because people of ordinary skill in the art would have understood that abiraterone can be co-administered with prednisone for patients with metastatic castration resistant prostate cancer

("mCRPC"). (See Complaint, ¶¶ 75-76, 78, 101-103) Accordingly, the patent application should have been rejected by the Patent Office—and for years, it repeatedly was rejected. (*Id*., ¶¶ 75-81)

Second, on or around June 4, 2013, to overcome the latest rejection of the application, J&J falsely represented to the Patent Office that Zytiga was commercially successful because it outperformed its closest competitors for market share, and this success was attributable to the claimed invention of abiraterone administered together with prednisone—a so-called "secondary consideration" that enabled Defendants to overcome the obviousness objection. (Complaint, ¶¶ 64-66, 82-83) These assertions were false because Defendants misrepresented Zytiga's market share performance against competitors. Defendants also failed to disclose that Zytiga's purported commercial success was not attributable to co-administration with prednisone, but instead to other factors that Defendants omitted. (*Id*., ¶ 84)

Most glaringly, Defendants falsely claimed that Zytiga had gained significant market share in the market for chemo-naïve (*i.e.*, patients who have not received chemotherapy) mCRPC patients against Xtandi® and bicalutamide. (Complaint, ¶¶ 82-84) But Defendants omitted that Xtandi—Zytiga's principal competitor—was not FDA-approved for the chemo-naïve market during the time specified by Defendants. (*Id.*, ¶ 84(a)) Defendants knew this omission was important: In the same submission, Defendants justified Zytiga's declining market share for a certain indication by emphasizing the FDA approval dates of Zytiga compared with its competitors for that indication that supposedly explained Zytiga's poor market share performance. (*Id.*, ¶ 84(b)-(d)).

Defendants also failed to disclose that Zytiga's commercial success directly resulted from a blocking patent, U.S. Patent No. 5,604,213 ("the '213 Patent'"), which expired in December 2016, that deterred competitors from introducing generic abiraterone acetate prior to that date. (Complaint, ¶¶ 8, 62, 87(e)) The import of the blocking patent was clear, as recognized by the

PTAB, this Court, and the Federal Circuit in decisions rejecting Defendants' commercial success argument and holding the '438 patent invalid. *See Wockhardt Bio AG v. Janssen Oncology, Inc.*, No. IPR2016-01582, 2018 WL 456328, at *16 (P.T.A.B. Jan. 17, 2018); *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 352 F. Supp.3d 352, 387 (D.N.J. 2018); *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063, 1076 (Fed. Cir. 2019). Defendants knew the blocking patent was largely responsible for Zytiga's claimed commercial success. (Complaint, ¶ 87(e))

The Complaint also alleges numerous other material facts relating to commercial success that Defendants should have, but did not, disclose to the Patent Office. (*Id.*, ¶¶ 84, 87) These omissions were likewise made knowingly or recklessly. (*Id.*) And by making them, Defendants violated their regulatory "duty of candor and good faith," which requires each "individual associated with the filing and prosecution of a patent . . . to disclose to the Office all information known to that individual to be material to patentability." 37 C.F.R. § 1.56; *see also* Manual of Patent Examining Procedure § 2001.04 (describing obligation in detail).

Third, Defendants' fraudulent June 4, 2013 submission with respect to Zytiga's relative market share performance against competitors and commercial success arising from the coadministration of abiraterone with prednisone misled the Patent Office into issuing the '438 patent. (Complaint, ¶¶ 85-86, 88-90) But for these misrepresentations, the Patent Office would have rejected the application as obvious, and the patent monopoly protecting Zytiga would have ended by December 2016, when the '213 patent expired. (Id., ¶¶ 88-90, 93) Indeed, the regulation establishing the duty of candor and good faith provides expressly that "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct." 37 C.F.R. § 1.56.

Fourth, generic manufacturers have been ready to enter the market since December 2016, but they have been prevented from doing so because of Defendants' fraudulent scheme.

(Complaint, ¶¶ 92-105) After obtaining the '438 patent, Defendants listed it in the FDA's Orange Book. (*Id*., ¶ 92) This is significant because a generic manufacturer seeking FDA approval of an Abbreviated New Drug Application ("ANDA") must certify that the generic drug will not infringe a patent listed in the Orange Book. (*Id.*, ¶ 48) If the brand drug is covered by a patent that has not yet expired, then a generic manufacturer must submit a so-called Paragraph IV certification, which states that the listed patent is invalid or will not be infringed. (*Id*., ¶¶ 48, 50, 98) When a generic manufacturer files a Paragraph IV certification, the brand-name manufacturer can immediately sue the generic manufacturer for infringement—and by statute, the initiation of such litigation delays FDA approval of the ANDA for at least 30 months. (*Id*., ¶ 51) In this case, Defendants used this procedure to assert the '438 patent in several objectively baseless infringement actions to prevent generic manufacturers from entering the market. (*Id.*, 99)

Fifth, Defendants' conduct unlawfully propped up the market price of Zytiga. The entry of generic competitors would have caused Zytiga's price to drop by at least 85%, and Defendants would have lost 90% of Zytiga's market share. (*Id.*, ¶¶ 8, 55)

Sixth, Defendants used the tainted market price for Zytiga to manipulate the prices the government paid for the drug. Indeed, the principal target of Defendants' fraud was the government, because government programs pay for 80% of Zytiga prescriptions in the United States. (*Id.*, ¶ 6) As part of the process of obtaining eligibility for reimbursement under various federal health care programs, Defendants submitted Zytiga for listing on the Federal Supply Schedule ("FSS"). (*Id.*, ¶ 112) In that process, Defendants submitted the market prices for Zytiga to the government, which was required to ensure the government paid no more than the "fair and reasonable" price for Zytiga. *See* 48 C.F.R. §§ 8.404(d); 15.402(a) (2018). Defendants knew the market price of Zytiga was not fair and reasonable but was instead inflated by Defendants' fraud. (Complaint, ¶¶ 110, 117) These submissions resulted in the government paying more money for

Zytiga, as Defendants intended. (*Id.*, ¶ 132) Similarly, in negotiations with Medicare Part D providers, Defendants relied on the tainted market price for Zytiga to obtain more money than they otherwise would have. (*Id.*, ¶ 36) By inflating the market prices, Defendants also inflated the Federal Ceiling Price for most government agencies directly purchasing drugs, as well as the "Best Price" for Medicaid reimbursement for single-source drugs. (*Id.*, ¶¶ 112, 115)

Seventh, the government was harmed by Defendants' conduct. Government health care programs frequently favor less expensive generic drugs.[2] By unlawfully excluding generic competitors from the market altogether, Defendants denied these government programs that choice, and therefore deprived the government of significant cost savings. (Complaint, ¶¶ 108-109) Defendants also ensured that the government would pay monopoly prices, as opposed to competitive market prices, for the drug. (*Id.*, ¶¶ 108-09, 124-125, 132)

The financial impact of Defendants' fraud was significant because the government is a major purchaser of Zytiga. Medicare Part D and Medicaid paid approximately $920 million in 2017 (the last date data is available) for Zytiga based on nearly 100,000 separate claims.[3] (Complaint, ¶ 7) Of that amount, $780 million was likely an overcharge. (*See* Complaint, ¶¶ 7, 55, 124-125) These amounts do not include direct government purchases, such as through the Veterans' Health Administration or TRICARE, or from Medicare Advantage. Thus, Defendants made substantially more money selling Zytiga to the government as a direct result of their fraud.

ARGUMENT

The Complaint alleges Defendants did three fraudulent things, each of which tainted

[2] For example, the Office of Inspector General of the DHHS has noted that the Centers for Medicare and Medicaid Services "strongly encourages the dispensing of generic drugs." *Generic Drug Utilization in State Medicaid Programs* (July 2006), at iv, available at https://oig.hhs.gov/oei/reports/oei-05-05-00360.pdf.

[3] The data can now be accessed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html.

claims for payment made to the government: (1) Defendants obtained the '438 patent through fraud on the Patent Office (Complaint, ¶¶ 63-91); (2) Defendants knowingly used the fraudulent patent to delay generic competition, inflating the market price and securing their market share (*id.*, ¶¶ 92-105); and (3) Defendants provided tainted and misleading pricing information to government payors, leading to contracts that caused the government to pay more for Zytiga than it otherwise would have (*id.*, ¶¶ 106-133). This gives rise to FCA liability under three theories.

First, Defendants are liable because their upstream frauds on the Patent Office and on government payors during pricing negotiations tainted downstream claims for payment. *See, e.g.*, *Campie*, 862 F.3d at 902 (explaining that under this theory, "subsequent claims are false because of an *original fraud* (whether a certification or otherwise)") (quotation marks omitted); *Garbe*, 824 F.3d at 645 (sham discount program that excluded a population of lower-paying customers, thereby inflating the reported market price of the drug, supported FCA liability for subsequent downstream claims); *Krahling*, 44 F. Supp.3d at 592 (defendants' false statements to the FDA to obtain approval for mumps vaccine supported FCA liability for subsequent claims for payment).

Second, Defendants implicitly certified the prices they were charging were not tainted by fraud. Any reasonable government payor would believe the prices it was paying reflected competitive market conditions—not fraud and an unlawful monopoly. This gives rise to a claim under the implied certification doctrine. *See Universal Health Servs., Inc. v. United States* ex rel. *Escobar*, 136 S. Ct. 1989, 2000-01 (2016); *Campie*, 862 F.3d at 901.

Third, in addition to making false claims to government payors, the application for the '438 patent is itself an actionable false claim. A "claim" under the FCA includes any "request" for "property"—and patents are property. *See* 31 U.S.C. § 3729(b)(2). By making misleading statements during patent prosecution, Defendants made false claims and used false statements and records in connection with those claims in violation of the FCA. *See* § 3729(a)(1)(A), (B). Those

falsities, which were made knowingly or recklessly, were material to the Patent Office's decision to grant the application for the '438 patent, and therefore give rise to FCA liability.

Each of these theories renders Defendants liable for the government's damages and civil monetary penalties.[4] Taking the allegations in the Complaint as true, none of Defendants' contentions justify dismissing this case at the pleading stage.

I. The Complaint Pleads Falsity

Defendants argue that the Complaint does not allege falsity in connection with a claim for payment (MTD 23-26), federal drug pricing (MTD 26-28), or promissory fraud (MTD 29-30). This structure of argument obfuscates more than it explains. The Complaint is clear about when, where, and how Defendants deceived the government: during patent prosecution, and during pricing negotiations. It is clear that these deceptions caused the government to pay hundreds of millions of dollars more for Zytiga than it should have paid, thus tainting those claims for payment. Under the theories summarized above, that is enough to plead that Defendants submitted "false or fraudulent" claims, and used false statements in connection with those claims—and therefore to state claims under the FCA.

A. Defendants' Fraud on the Patent Office Rendered Their Claims for Payment False or Fraudulent

The first theory of FCA liability is that Defendants' original fraud on the Patent Office—which allowed them to inflate the price that the government paid for Zytiga—tainted subsequent claims for payment involving that inflated price.

The FCA is broadly construed to apply to claims that are "false or fraudulent," 31 U.S.C.

[4] Defendants' knowing listing of the '438 patent in the Orange Book constituted an additional statement that was material to false claims because Defendants were required to list only those patents that "could reasonably be asserted" against generic competitors. *See* 21 U.S.C. § 355(b)(1). Defendants do not address this falsity, but it, too, precludes dismissal. 31 U.S.C. § 3729(a)(1)(B).

§ 3729(a)(1)(A), (B), and not only to claims that are literally false. This includes misleading omissions, *Escobar*, 136 S. Ct. at 1999; and it includes situations in which an original upstream fraud taints downstream claims, *Campie*, 862 F.3d at 903; *Hendow*, 461 F.3d at 1174; *Garbe*, 824 F.3d at 645; *Krahling,* 44 F. Supp. 3d at 592. *See also United States* ex rel. *Marcus v. Hess*, 317 U.S. 537, 539 & n.1, 542-44 (1943) (explaining that after defendants rigged bids to obtain contracts, the "fraud did not spend itself with the execution of the contract," because its "taint entered into every swollen estimate which was the basic cause for payment" downstream).

Defendants acknowledge that if a defendant secures a government contract by fraud, then every claim for payment under the contract is actionable under this theory. (MTD 29) They argue, however, that this theory is limited to claims pursuant to fraudulently obtained contracts. Not so. Courts have recognized that when a party uses fraud to secure any benefit from the government (*e.g.*, regulatory approval, or the right to participate in a government program), that fraud taints downstream claims for payment regardless of a specific agreement from which the claims arose.

The Ninth Circuit's decision in *Campie* is instructive. There, the relator alleged, among other things, that the defendant fabricated lab test results to deceive the FDA into approving the use of active pharmaceutical ingredients from a facility in China. The district court had held that "the FCA requires that" any false statement "be directed to the government as part of the reimbursement process" to be actionable. *United States* ex. rel. *Campie v. Gilead Scis., Inc.*, 2015 WL 106255, at *8 (N.D. Cal. 2015). The court accordingly found that false statements to the FDA were not actionable, because "false certifications, statements, or other fraudulent conduct directed at the FDA during the [drug] approval process do not render subsequent Medicare or Medicaid reimbursement requests made to CMS 'false' under the FCA." *Ibid*.

On the relators' appeal, the government as *amicus curiae* argued that "even when a claim is not false on its face and does not have a false certification, the claim can nonetheless be 'false or

fraudulent' within the meaning of the FCA when it is derived from, and closely connected to, a defendant's antecedent fraud." Gov't Br., 2016 WL 211750, at *12-13. The government explained that allegations of fraud on the FDA had "a sufficiently close connection" to government payments because "the effect of [the defendant's] fraud—enabling its drugs to qualify for (among other things) government payment—was not only natural and foreseeable, but was in fact the intended and primary reason for [the defendant's] conduct." *Id*. at *28.

The Ninth Circuit agreed and reversed, explaining that "the False Claims Act imposes no such limitation" requiring frauds to be perpetrated directly against paying agencies. *Campie*, 862 F.3d at 903. "It is not the distinction between the agencies that matters, but rather the connection between the regulatory omissions and the claim for payment." *Ibid*. Thus, when "a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork." *Ibid.* (*quoting Hendow*, 461 F.3d at 1174). Instead, the "subsequent claims are false because of an original fraud." *Id*. at 902. The appellate court accordingly held that fraud on the FDA gave rise to claims for both implied false certification and promissory fraud because the fraud, which rendered the drugs in question eligible for payments by the government, was connected to the later claims for payment.

Similarly, in *United States* ex rel. *Main v. Oakland City University*, 426 F.3d 914, 916 (7th Cir. 2005), the defendant university fraudulently obtained eligibility for educational subsidies by misrepresenting its recruitment practices. That application did not, itself, result in any payments to the university. Those came later, after the university and its students sought specific grants, loans, or scholarships. The district court had held that the university's initial fraud was not actionable under the FCA because it did not request "an immediate payment from the Treasury." *Ibid*. The Seventh Circuit reversed, holding that the fraud was "integral to a causal chain leading to payment," and therefore actionable. *Ibid*.

In *Krahling*, the court found that the defendants' fraudulent statements to the FDA to obtain approval for their mumps vaccine stated a valid FCA claim with respect to subsequent claims for payment, even though the FDA was not the paying agency. 44 F. Supp. 3d at 592. The court recognized liability arises when an original fraud taints subsequent claims, holding "that the fraud-on-the-FDA theory under the FCA withstands the motion to dismiss." *Id*.

This case is indistinguishable from the foregoing authorities. Defendants' fraud on the Patent Office enabled them to charge inflated prices for Zytiga to government payors. Indeed, the Complaint alleges that this overcharging was the "entire point" of the fraud. (Complaint, ¶ 108) When, as here, the causal connection between Defendants' fraud and subsequent claims for payment is clear, it would make no sense to hold the government has no remedy for its injury.

The district court recognized as much in *Amphastar Pharmaceuticals Inc. v. Aventis Pharma SA*, No. 5:09-cv-0023-MJG, 2013 WL 12139832 (C.D. Cal. Apr. 19, 2013), *vacated on other grounds*, 2015 WL 4511573, *vacatur aff'd*, 956 F.3d 696. There, the plaintiff alleged the defendant used a "fraudulently-obtained patent" to obtain an "exclusive market position" for a drug, charging the United States an "inflated price" for the drug, which the "Government paid." The court held that "[t]hese allegations are sufficient to present an adequately pleaded plausible claim that Aventis submitted, and/or caused to be submitted, false claims to the United States in connection with the alleged scheme."[5] *Id*. at *3.

[5] The *Amphastar* complaint was later dismissed on public disclosure grounds, 2015 WL 4511573, and the Ninth Circuit affirmed that dismissal without commenting on the merits. *Amphastar Pharms., Inc. v. Aventis Pharma SA*, 856 F.3d 696 (9th Cir. 2017). As explained in § V, *infra*, the disclosure that prompted dismissal in *Amphastar*—filings in private civil litigation—no longer qualifies as a public disclosure after the 2010 amendments to the statute. Accordingly, that dismissal does not help Defendants here.

In the public disclosure dismissal order, the *Amphastar* court noted that a law review article had questioned the validity of Amphastar's theory. The article—written by a law student and two firm associates, one of whom represented pharmaceutical companies in patent prosecution—concedes,

Defendants nevertheless argue that the "upstream fraud" or "promissory fraud" theory applies only to fraudulent attempts to obtain a government contract. (MTD 29-30) This is unpersuasive. First, even if Defendants were correct about the law, the Complaint meets this requirement because it alleges that Defendants sold Zytiga to various government programs pursuant to a Master Agreement ("MA") and a Pharmaceutical Price Agreement ("PPA") that were tainted by fraud. (Complaint, ¶ 112, *citing* 38 U.S.C. § 8126(a))

More fundamentally, Defendants are wrong about the law. There is no textual basis to limit fraud-in-the-inducement claims to contracts. The statutory definition of a "claim," which includes requests for money or property "*whether under a contract or otherwise*" strongly suggests that such a limitation would be wrong. 31 U.S.C. § 3729(b)(2)(A) (emphasis added). The Supreme Court has likewise refused to adopt "a circumscribed view" of falsity under the FCA. *Escobar*, 136 S. Ct. at 2002. Indeed, for decades, the Court has recognized that Congress's purpose in the FCA was "to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *Hess*, 317 U.S. at 544–45. Of course, cases like *Campie*, *Krahling*, and *Amphastar*—which were not predicated on fraudulently obtained contracts—also reject Defendants' "contracts only" limitation.

The case Defendants cite, *In re Plavix Marketing, Sales Practice and Products Liability Litigation*, 332 F. Supp. 3d 927, 952 (D.N.J. 2017), is distinguishable. There, the court found that the complaint did not allege any "causal connection" between the alleged fraud—misstatements made to a formulary committee that rendered a drug automatically eligible for Medicaid reimbursement—and claims for payment. Here, however, the Complaint alleges that Defendants'

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however, that Congress's amendments broadening the FCA have "made claims like Amphastar's feasible." Gregory Michael, *et al.*, *The New Plague: False Claims Liability Based on Inequitable Conduct During Patent Prosecution*, 25 Fordham Intell. Prop. Media & Ent. L.J. 747, 784 (2015).

fraud on the Patent Office was intended to and did cause the government to pay more for Zytiga than it otherwise would have. (*See, e.g.*, Complaint, ¶¶ 108, 124, 132) *Plavix*'s discussion of cases involving upstream frauds was incomplete, and the cases it relied upon refute Defendants' argument. Importantly, *Plavix* never cited or discussed *Campie* at all. Instead, it addressed a single case in which the relator alleged the defendant had defrauded the FDA but conceded causation. *See Plavix*, 332 F. Supp. 3d at 956-59 (citing *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016)). But *D'Agostino* does not stand for the proposition that a non-contractual fraud does not give rise to a "fraudulent" claim; it stands for the proposition that causation is an element of the FCA. The Complaint here pleads causation, so *D'Agostino* does not weigh in favor of dismissal. Under the facts alleged in the Complaint, *Campie*, *Main*, *Krahling*, and *Amphastar* are the better-reasoned, and more applicable, authority.

Defendants also cite *United States* ex rel. *Promega Corp. v. Hoffman-La Roche Inc*., No. 03-1447-A (E.D. Va. Sept. 24, 2004), for the proposition that the fraud on the Patent Office is too "disconnected" from the inflated invoices to be actionable under the FCA. (MTD 29-30) In *Promega*, the court found "a disconnect between the alleged misrepresentations to the [Patent Office] and the invoices submitted to the Government." (MTD, App. A, at 5). The relators had attempted to articulate the connection "by claiming that the misrepresentations somehow induced the Government to enter into contracts with the Defendants." (*Ibid*.) The relators "failed, however, to allege any facts that support such a theory," and so the complaint failed under Rule 9(b). (*Ibid*.) That holding applies only to the specific facts alleged in *Promega*, and no court has ever relied on *Promega* for the broader argument on proximate causation Defendants make here. The Complaint in this case is manifestly different, because it explains how Defendants' fraud affected government contracting and resulted in the government paying higher prices for Zytiga.

Promega's "circumscribed" reading of falsity has also been repudiated by well-reasoned authority decided in the 15 years since *Promega* was decided. *See, e.g.*, *Escobar*, 136 S. Ct. at 2002; *Amphastar*, 2013 WL 12139832 (fraud on the Patent Office taints subsequent claims); *Campie*, 862 F.3d at 903 (fraud on the FDA taints subsequent claims)*; Krahling*, 44 F. Supp. 3d at 592 (same); *Hendow*, 461 F.3d at 1174 (fraud on the Department of Education tainted subsequent claims for payment). The court should follow the foregoing authority, and not the unpublished, outdated decision in *Promega*, which the court has removed from PACER.[6]

B. Defendants' Pricing Fraud Rendered Their Claims False or Fraudulent

To list Zytiga on the FSS (a precondition for reimbursement under many government programs), and to otherwise set the price that government payors would pay for Zytiga, Defendants communicated Zytiga's market price to the government, knowing that the government would derive a "fair and reasonable" price from this input. (Complaint, ¶¶ 106-117) Defendants knew, however, that they were using an unlawfully inflated market price to inflate the price the government paid for Zytiga, but never disclosed that information. (*Id.*, ¶¶ 110, 117) For the reasons given above, this antecedent fraud rendered subsequent claims for payment false.

This misconduct also gives rise to liability under an implied certification theory because the claims for payment implicitly certified that the price was reasonable, when Defendants knew otherwise. In *Escobar*, the relator alleged that claims submitted to Medicaid for counseling services were "false and fraudulent" under the FCA when the claims referred to billing codes corresponding to services such as "family therapy" and job titles such as "Social Worker, Clinical." 136 S. Ct. at 1997. The Supreme Court held that the claims were actionable because the use of the billing codes was "clearly misleading in context. Anyone informed that a social worker

[6] Moreover, questions concerning whether the fraud is too "disconnected" or attenuated from the government's injury is a question of fact that cannot be resolved as a matter of law on a Rule 12 motion. *See United States v. Celgene Corp.,* 226 F. Supp. 3d 1032 (C.D. Cal. 2016).

at a Massachusetts mental health clinic provided a teenage patient with individual counseling services would probably—but wrongly—conclude that" the social worker was qualified and licensed under Massachusetts law. *Id.* at 2000. The social worker was not licensed in Massachusetts, and therefore the use of the billing codes "without disclosing [the defendant's] many violations of basic staff and licensing requirements . . . constituted misrepresentations" actionable under the FCA. *Id*. at 2000-01.

The facts alleged in the Complaint compare favorably with *Escobar*. When Defendants sought payment for Zytiga, they knew the government would only pay a "fair and reasonable" price for it—and they also knew they had tainted the pricing negotiations using a fraudulently inflated market price for Zytiga. (Complaint, ¶¶ 9, 106-117, 124, 131-132) Anybody receiving Defendants' reported "lowest price charged to any commercial customer" would probably—but wrongly—conclude that such price reflected fair market conditions. (*See id.*, ¶¶ 112, 117, 131) This is especially true because the government's specific instructions made absolutely clear that Defendants' reported price would serve as the basis for ensuring the price the government was charged for the medicine remained "fair and reasonable throughout the life of the contract." (*Id.*, ¶ 112) When Defendants then submitted claims for payment—at the resulting prices—they implicitly reaffirmed they had not inflated the prices by fraud. That affirmation was false.

Defendants argue that the implied certification doctrine does not apply because, according to them, the General Services Administration ("GSA") is indifferent about whether the prices the government pays are actually "fair and reasonable." (MTD 27) All the GSA wants to know, say Defendants, is whether the government is paying the same prices as commercial payors: So long as a seller accurately reports the prices it charges to commercial payors, it has satisfied all of its regulatory obligations—even if that price is tainted by fraud. (*Id.* at 27-28)

That is absurd. Defendants are contending that the government does not care if it gets ripped off, so long as others also get ripped off. No reasonable payor would take that position. Specifically, no reasonable payor would be indifferent about paying a price for drugs that had been inflated 650% due to fraud. (*See* Complaint, ¶¶ 8, 55, 124-131).

In making this argument, Defendants correctly describe the information the government collects—but ignore altogether the *reasons* the government collects it. The government seeks information about what commercial payors are paying because it assumes that commercial payors are paying fair market value. *Cf.* 48 C.F.R. § 15.402(a)(2)(i) (providing that no additional cost or pricing data to establish "fair and reasonable price" is necessary if the price is "based on adequate price competition"). But when, as here, a defendant knows that it has distorted the market price through a fraudulently obtained patent monopoly, the defendant knows the government's reasonable assumption is false. In this context, blithely reporting the prices that commercial payors pay—without disclosing that the prices have been unlawfully inflated—is precisely the same sort of misleading half-truth the Supreme Court found actionable in *Escobar*.

For similar reasons, Defendants' argument that to state an implied certification claim, the claim must make a specific representation about the goods and services provided is unpersuasive. (MTD 24-26) In pricing fraud cases generally, a defendant's misrepresentation typically will be that an inflated price is the true price. That happened here—and the fact pattern fits the Supreme Court's description of a "half-truth." *Escobar*, 136 S. Ct. at 2000.

Moreover, as Defendants themselves acknowledge, courts in this district have rejected the argument that a claim must make specific representations about goods or services to be actionable. *See United States ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 408 (D.N.J. 2019) (collecting cases). As the Supreme Court explained in *Escobar*, implied false certification claims are available "at least" where the claims involve specific representations—but "at least"

does not mean "only." *Escobar*, 136 S. Ct. at 2001. (In any event, the inflated prices for Zytiga *are* representations "about the goods and services provided." *Id.*; *see also* § II, at 22, *infra.*)

Defendants also make slippery-slope arguments, contending that recognizing liability in this case would inappropriately expand the FCA. (*See, e.g.*, MTD 26-29) The Court should reject these arguments. The Third Circuit recently explained that arguments about litigation "floodgates" are unpersuasive because the government has the power to dismiss FCA actions that impair its interests. *Bookwalter* 2019 WL 4437732, at *16. Moreover, recognizing liability here would not lead to liability any time a patent is challenged or found to be invalid—or any time a defendant violates a regulation that may affect drug pricing—because the FCA requires a relator to prove fraud, and not merely a regulatory violation.

Defendants' argument also ignores the more dangerous slippery-slope risk in the other direction. The FCA was designed to address every fraudulent scheme that might result in a financial loss to the government. Here, Defendants' scheme deprived the government of hundreds of millions of dollars and drove up the cost of healthcare for patients with a particularly severe form of cancer. Construing the FCA narrowly to carve out claims like this one would give drug manufacturers a green light to continue defrauding the Patent Office, confident that the government would have no effective remedy against their malfeasance, to the detriment of the public fisc and patients.

C. The Fraudulent Patent Application Is a False Claim

Independently, the Court should hold that the fraud on the Patent Office was actionable under the FCA even apart from its effect on downstream claims. While most FCA claims are predicated on claims for payment of money, the statute sweeps more broadly. Thus, a "claim" is defined as "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—(i) is presented to an

officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2)(A). An application for a patent fits this definition of a "claim" because it is a "request" for "property" that is "presented to an officer, employee, or agent of the United States."

Patents are described as "intellectual property," because by their terms, patents "claim" inventions from the public domain for the exclusive benefit of the patentee. As the Supreme Court has explained, patents create a property right in the form of a public franchise. *See Oil States Energy Servs., LLC v. Greene's Energy Grp.,* LLC, 138 S. Ct. 1365, 1373-75 (2018).[7] Indeed, the Patent Act provides that "[s]ubject to the provisions of this title, patents shall have the attributes of personal property." 35 U.S.C. § 261. Thus, patent owners have the powers associated with property, including the power to exclude others from practicing their inventions.

J&J's fraudulent application for the '438 patent therefore violated the FCA. It is a false or fraudulent claim, and J&J used false statements in connection with that claim.[8] J&J is accordingly

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[7] The Supreme Court has confirmed repeatedly that patents are property. *See, e.g.*, *Mission Prod. Holdings, Inc. v. Tempnology, LLC*, 139 S. Ct. 1652, 1659 (2019).

[8] Defendants may cite *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1380 (Fed. Cir. 2000), *amended* (Apr. 5, 2000). There, the Federal Circuit held that inequitable conduct on the Patent Office could not establish the predicate offenses of mail fraud and wire fraud for a RICO claim. For those statutes, a claim for fraud requires the defendant to deprive the victim of property the victim possessed, but an unissued patent is not property in the government's hands. *See id.* The court also rejected the claimant's "attempt to analogize a patent to a franchise," which would have supported a fraud claim. *Id*.

For two reasons, *Semiconductor Energy Laboratory* does not control and is not persuasive.

First, the mail and wire fraud statutes are different from the FCA. Those laws have long been interpreted narrowly to apply only to schemes to take property in the victim's hands. *See McNally v. United States*, 483 U.S. 350, 360 (1987); *Cleveland v. United States*, 531 U.S. 12, 19-20 (2000). In contrast, the FCA is construed "broadly" to achieve its remedial purpose. *Campie*, 862 F.3d at 899. Congress also broadened the FCA in 2009 by adding the phrase "whether or not the United States has title to the money or property" to the definition of a "claim," confirming that the FCA is not limited to attempts to obtain property in the government's hands. 31 U.S.C. § 3729(b)(2)(A). The narrow understanding of fraud embodied in the mail and wire fraud statutes is therefore inapplicable to the FCA. *Cf. Loughrin v. United States*, 573 U.S. 351, 360 (2014).

Second, the Supreme Court has subsequently rejected the essential holding of *Semiconductor Energy* that a patent is not a franchise. *See Oil States*, 138 S. Ct. at 1373.

liable for civil monetary penalties plus three times the damages sustained "because of [J&J's] act." 31 U.S.C. § 3729(a)(1). That includes the monopoly premium the government paid for Zytiga after December 2016.

II. The Complaint Pleads Materiality

The FCA's standard for materiality means "having a natural tendency to influence, or be capable of influencing, the receipt of money or property." 31 U.S.C. § 3729(b)(4). As the Supreme Court has explained, a matter is material if a reasonable person would attach importance to it, or if the defendant knew or had reason to know that the government would attach importance to it, even if a reasonable person would not. *See Escobar*, 136 S. Ct. at 2002-03. The Court in *Escobar* clarified that materiality is a holistic inquiry: A court evaluating materiality should consider, *inter alia*, whether the noncompliance is minor or insubstantial or if it goes to the very essence of the bargain; whether the Government has expressly identified a provision as a condition of payment; and whether the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement, or if, with actual knowledge of the non-compliance, it consistently pays such claims with no indication that its practice will change. *See Escobar*, 136 S. Ct. at 2003 & n.5. None of these considerations is dispositive alone, nor is the list exclusive. At the pleading stage, a Complaint need not discuss every factor. It is enough for the complaint to plead facts that give rise to a plausible inference of materiality. *See United States* ex rel. *Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 834-35 (6th Cir. 2018).

The Complaint pleads materiality in two ways. First, it pleads that the fraud on the Patent Office caused the government to issue the '438 patent. (Complaint, ¶¶ 63-90) That allegation is certainly plausible, because the federal regulation setting forth the duty of candor and good faith establishes that violations of that duty are bars to patentability. 37 C.F.R. § 1.56. Here, the Patent

Office previously rejected the application for obviousness, reversing course only after Defendants misrepresented that Zytiga's commercial success was attributable to the claimed invention. (Complaint, ¶¶ 64-65, 75-90) That is sufficient at the pleading stage with respect to the theory that the fraud on the Patent Office was itself a false claim.

Second, the Complaint pleads that Defendants' fraud was material to the government's payment decisions. (Complaint, ¶¶ 120-132) A reasonable payor would not want to pay inflated prices for drugs—and the government behaves reasonably in this regard by encouraging generic competition to brand-name drugs, and by buying cheaper drugs when they are available. (*Id.*, ¶¶ 44-47, 57, 109) The Complaint pleads representative examples of when the government has taken enforcement actions to ensure adequate price competition from generic manufacturers. (*Id.*, ¶¶ 127-130). The government has also successfully pursued claims based on fraud on the Patent Office that excluded generic competition.[9] The government has expressed time and again its desire to pay less for prescription drugs, and many government health plans require the purchase of generics when they are available.[10] (*Id.*, ¶ 109) Consequently, there is no doubt that if Defendants had not fraudulently excluded generics from the market, the government would have bought abiraterone acetate from those companies at lower prices instead of from Defendants.

More broadly, the price of drugs goes to "the essence of the bargain" between drug manufacturers and the government. Price is a quintessential material contract term. J. D. Calamari & J.M. Perillo, *The Law of Contracts*, § 2-13, at 43-44 & n. 17 (2d ed. 1977); *see Unihan Corp. v. Max Group Corp*., 2011 WL 6814044, at *7 (C.D. Cal. 2011) (price of a product is a material

[9] *See*, *e.g.*, *F.T.C. v. Cephalon, Inc.*, 36 F. Supp. 3d 527, 534 (E.D. Pa. 2014) ("The conclusion that Cephalon committed fraud on the Patent Office is significant because patents procured by fraud do not, as a general rule, provide a defense under the antitrust laws").

[10] *See, e.g.*, Centers for Medicare & Medicaid Services, Your Guide to Medicare Prescription Drug Coverage, https://www.medicare.gov/pubs/pdf/11109-Your-Guide-to-Medicare-Prescrip-Drug-Cov.pdf, at 29; *see also* n. 1, *supra*.

contractual term). Courts have held that terms affecting the size of government payments are material under the FCA. *See United States* ex rel. *Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 701 (S.D.N.Y. 2018) (misstatement of information that directly influences the amount the government pays is material); *United States v. DynCorp Int'l, LLC*, 253 F. Supp. 3d 89, 102 (D.D.C. 2017) (claimed costs "were significantly higher than reasonable" and therefore material); *United States v. Rite Aid Corp.*, 2018 WL 1744796, at *7 (E.D. Mich. Apr. 11, 2018) (inflating usual and customary prices "would have the 'natural tendency to influence, or be capable of influencing,' the amounts reimbursed by CMS.") (citation omitted).

The Seventh Circuit's decision in *Garbe*, 824 F.3d 632, is particularly instructive. There, the defendant told the government its "usual and customary price" for drugs was a relatively high number—when in fact the reported prices were inflated because defendants' prescription program excluded purchases made by lower-paying cash customers in calculating the prices. The Seventh Circuit held that this was pricing fraud, and that it was material. The court rejected defendant's argument that the overcharges were not material, because the "allegedly false claims were material to [defendant's] receipt of more money than it should have gotten." *Id*. at 639. The court analogized to the tax fraud statute, which includes an identical definition of materiality, and under which "any failure to report income is material." *Id.* The court concluded that when false "claims were the basis of federal monies [the defendant] received," they were material for that reason. *Id.*

Defendants make a perfunctory argument about materiality, focusing on the fact that the government has continued to pay for Zytiga, and that it did not intervene here. (MTD 7-8, 30-32)

Continued payments do not help Defendants here for several reasons. First, even if the government continues to pay claims with knowledge of a violation, that is not dispositive of the holistic materiality inquiry. Second, there is no allegation that any paying agency had actual knowledge of Defendants' violations at the time payments were made. *See Prather*, 892 F.3d at

834 ("Without actual knowledge of the alleged non-compliance, the government's response to the claims submitted by the defendants . . . has no bearing on the materiality analysis."); *United States* ex rel. *Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) ("[M]ere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance."); *United States* ex. rel. *Armstrong v. Andover Subacute & Rehab Center Services One, Inc.*, 2019 WL 4686963, at *6 n. 16 (D.N.J. Sept. 26, 2019). Third, even when the government pays with knowledge of a violation, it may have good reasons unrelated to materiality to do so (*i.e.*, to ensure cancer patients get treated). *See Campie*, 862 F.3d at 906.

Defendants' reliance on the government's intervention decision is even less persuasive. There are myriad reasons why the government does not intervene in cases that have nothing to do with materiality or the merits, and courts generally refuse to accept that the government's intervention decision carries any weight in the inquiry. *See, e.g.*, *United States* ex rel. *Chandler v. Cook Cty., Ill.,* 277 F.3d 969, 974 (7th Cir. 2002), *aff'd*, 538 U.S. 119 (2003); *United States* ex rel. *El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 21 (D.D.C. 2008).

Because it is at least plausible that Defendants' fraud—which the Complaint alleges had a massive effect on the price the government paid for these drugs—was material to the government's payment decisions, Defendants' materiality arguments should be rejected.

III. The Complaint Pleads False Claims With Sufficient Particularity

A. Relator Adequately Pleads the Submission of a False Claim

The Complaint need only plead "particular details of a scheme" with "reliable indicia that lead to a strong inference" that claims have been submitted. *Foglia v. Renal Ventures Mgmt*., LLC, 754 F.3d 153, 156 (3d Cir. 2014). Requiring more "would be 'one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates.'" *Id.*, *citing United States*

ex rel. *Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); and *Ebeid* ex rel. *United States v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010).

The purpose of Rule 9 is to provide defendants with sufficient notice of the fraud alleged in the complaint. *See Bookwalter*, 2019 WL 4437732, at *15; *accord*, *United States* ex rel. *Integra Med Analytics LLC v. Providence Health & Servs*., 2019 WL 3282619, at *21 (C.D. Cal. July 16, 2019). The Complaint's allegations easily meet that standard.

The Complaint adequately alleges the "who, what, when, where, and how" of the fraud. The "who" includes, without limitation, Alan H. Auerbach, Arie S. Belldegrun, Andrea Jo Kamage, and the patent attorneys who submitted the misleading declarations on behalf of, and as agents for, J&J. (Complaint, ¶¶ 67-74). The "what" and "when" is the fraudulent June 4, 2013 submission to the Patent Office that was critical in misleading the Patent Office to grant the '438 patent (*Id.*, ¶¶ 82-90). The "where" is the Patent Office and J&J's headquarters, from where the fraudulent submissions were mailed. (*See, e.g., Id.*, ¶¶ 22, 70-71, 82). The "how" is Defendants' misleading the Patent Office by making false representations concerning the relative market share success of Zytiga compared with competitors and the omission of crucial information, such as the FDA approval dates of Zytiga's competitors during the relevant time period; or the blocking nature of the '213 patent that was critical to assessing Defendants' claimed commercial success. (*See, e.g., id.*, ¶¶ 82-87). Similarly, the Complaint pleads sufficient detail to put Defendants on sufficient notice with respect to the fraudulent pricing information submitted in connection with Zytiga's listing of the drugs on the FSS (*Id.*, ¶¶ 106-117).[11] The Complaint also alleges reliable "indicia" that false claims were submitted, detailing tens of thousands of false claims for Medicare and Medicaid. (*See, e.g.*, *Id.*, ¶¶ 6-7, 11, 118)

[11] The FSS schedule confirming the listing for Zytiga, and providing specific detail concerning, *inter alia*, the vendor responsible for the listing (J&J), the date, and the price, can be accessed and downloaded in Excel format at: https://www.va.gov/opal/nac/fss/pharmPrices.asp.

Any more detail is unnecessary here, because, like the allegations in *Bookwalter,* the Complaint pleads the falsity of *every single* claim for payment for Zytiga arising from "a set of circumstances that, if true, makes a whole set of claims at least *prima facie* false." *Bookwalter*, 2019 WL 4437732, at *15. And the Complaint is much more detailed than the allegations that the *Integra* court found sufficient. The *Integra* court held that even though the allegations in the complaint did not identify the precise individuals submitting false statements, the complaint nevertheless had sufficient detail to permit Defendants to "easily determine[]" who they were, and "therefore [such detail] did not need to be alleged in the complaint." 2019 WL 3282619, at *21.

The Complaint also compares favorably to the complaint found sufficient in *Amphastar*. There, the court originally found the complaint failed under Rule 9(b), but it reached the opposite conclusion after the relator added CMS data quantifying reimbursements for the drug.[12] *See* 2013 WL 12139832*,* at *3. The court explained that even though the relator had "not provided a detailed account of Aventis's claims submission process, nor specifics how government reimbursement programs work," such detail was "not necessary" because [t]he factual allegations present a plausible contention that *every claim* for reimbursement at the inflated price was an actionable false claim and the fact of payment by the United States . . . presents a quite reasonable—if not compelling—inference that there were claims leading to the payments." *Ibid*. This was "sufficient at the pleading stage" to support the relator's allegations that fraud on the Patent Office creates FCA liability when the government pays for drugs based on prices inflated by the exclusion of generic competitors. *Ibid*., at *3. Like the complaint in *Amphastar* (and *Bookwalter*), the Complaint here makes the key allegation that every claim for payment submitted with an inflated price was false. But the Complaint also does more: it provides specific allegations concerning "fair

[12] The only allegation concerning the submission of false claims in the original *Amphastar* complaint was an allegation "[o]n information and belief" that the defendant "used its illegal monopoly to overcharge the United States government." *Amphastar*, 09-cv-0023, Dkt. 1, at ¶ 28.

and reasonable" pricing under the FSS, the specific mechanics and magnitude of the overcharges, and pricing for Medicare and Medicaid generally—which the court in *Amphastar* found missing but not necessary.

Finally, Defendants wrongly argue the Complaint fails to allege Defendants' intent under Rule 9(b). The rule expressly provides that knowledge can be pleaded "generally." Fed. R. Civ. P. 9(b). *See also Integra*, 2019 WL 3282619, at *22 (complaint sufficiently alleged defendants were seeking to increase Medicare revenue and were reckless).

B. Relator Need Not Plead Inequitable Conduct

Defendants argue the Complaint fails to plead "inequitable conduct" with the requisite specificity under Rule 9 (MTD 1, 32-36), but Defendants rely on the wrong legal standard. Inequitable conduct is an affirmative defense to patent infringement, and it has been described as "the 'atomic bomb' of patent law" because it "render[s] the entire patent," as opposed to individual claims, "unenforceable"; and it can "spread from a single patent to render unenforceable other related patents and applications in the same technology family," endangering "a substantial portion of a company's patent portfolio." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (citation omitted). These and other concerns led the Federal Circuit in *Therasense* to "tighten[] the standards for finding both intent and materiality" in inequitable conduct defenses. *Id*. at 1290. They are inapplicable to FCA claims.

Defendants say that Relator must prove "specific intent" because an inequitable conduct affirmative defense requires it (MTD 33), but the FCA has its own, statutory standards for intent and materiality, which are looser than the standards for inequitable conduct. The FCA's intent standard can be satisfied by intentional conduct or by recklessness, and it requires "no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1). It is also well-established that a misleading omission is actionable as fraud. *See, e.g., Escobar*, 1989 S. Ct. at 1999. There is no justification

for applying a judge-made standard developed in a different context when Congress has affirmatively and explicitly provided otherwise. Moreover, it is sensible that the FCA standard would be looser than the standard available to private litigants generally: Congress was particularly concerned about fraud that harms the government.

Even considering the matter through the lens of inequitable conduct, Defendants' argument is wrong. The Complaint alleges with particularity that J&J *intentionally* misstated Zytiga's commercial success and misleadingly omitted material information *because* J&J knew that such disclosures would scuttle their application. (Complaint, ¶¶ 82-88). Such allegations easily demonstrate a "deliberately planned and carefully executed scheme" to fraudulently obtain a patent for the purpose of excluding competitors and artificially raising or maintaining prices for Zytiga. *See Therasense*, 649 F.3d at 1290 (internal citations omitted); *see also Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 2005 WL 8156817, at *3 (C.D. Cal. May 2, 2005) (false statements concerning commercial success was "clear and convincing evidence of inequitable conduct").

Under 37 C.F.R. § 1.56, "intentional misconduct" is a bar to patentability. At the pleading stage, J&J's assertions that they did not act intentionally cannot be credited because the Complaint's allegations of intentional misconduct plausible in light of previous rejections by the Patent Office of J&J's "commercial success" submissions. And these sort of scienter questions are typically matters for a trier of fact, even in inequitable conduct cases (and certainly in FCA cases). *See, e.g.*, *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*, 90 F. Supp. 2d 522, 528 (D.N.J. 2000) ("[A] fact finder may infer deceptive intent when a patent applicant withholds potentially pertinent information and makes arguments for patentability which could not have been made had the information been disclosed."); *Skedco, Inc. v. Strategic Operations, Inc.*, 287 F. Supp. 3d 1100, 1149–1150 (D. Or. 2018) (denying summary judgment against inequitable conduct defense even though the applicant had disclosed relevant patents in the same application).

Although not necessary, Relator also sufficiently pleads "but-for" materiality as a matter of patent law. For withheld information to be deemed material for inequitable conduct, the information must not be cumulative of information on record with the USPTO, and it must either establish a *prima facie* case of unpatentability of a claim; or refute, or be inconsistent with, a position asserted to obtain a patent. *See Purdue Pharma, L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123 (Fed.Cir.2006) (*quoting* 37 C.F.R. § 1.56(a)). The Complaint alleges with specificity that the Patent Office had rejected numerous times the application for the '438 patent (Complaint, ¶ 75); the patent Examiner specifically instructed Defendants to provide relative market share comparisons if they wished to demonstrate "commercial success" necessary to have the patent issued (*id.*, ¶ 80); and Defendants' misleading statements in the June 2013 submission in response to the Examiner's instructions were the "but-for" cause for the issuance of the '438 patent (*id.*, ¶¶ 85-86).

Moreover, Defendants' fraud is not simply a garden-variety instance of withholding prior art, but rather affirmatively lying to the Patent Office by suggesting that Zytiga's commercial success was due to its co-administration with prednisone. Misrepresented information is necessarily material if a court invalidates a patent based on such information. *Therasense*, 649 F.3d at 1292 ("if a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material"). Here, this Court, the PTAB, and the Federal Circuit considered information identified in the Complaint, such as the blocking nature of the '213 patent, as sufficient to overcome Defendants' commercial success argument. *See, e.g., BTG*, 352 F. Supp.3d at 386-87; *Wockhardt,* 2018 WL 456328, at *16; *BTG,* 923 F.3d at 1076.

Finally, Defendants say that inequitable conduct imposes the duty of "candor and good faith" on individuals filing documents with the Patent Office, and not on corporations. (MTD 33) Defendants argue that the Complaint does not plead specific individuals who prosecuted the '438

patent on behalf of J&J had "specific intent"[13] to deceive. (MTD 33-34, *citing* to inequitable conduct cases) This simply ignores the detailed pleading in ¶¶ 63 through 82 of the Complaint.

In any event, J&J is properly chargeable with the fraud. *See Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010) ("If an individual who is substantively involved in the preparation or prosecution of an application fails to comply with his duty of candor, then that individual's misconduct is chargeable to the applicant for the patent, and the applicant's patent is held unenforceable.").

The Complaint alleges that J&J, as the real parties-in-interest of the '438 patent, obtained it through fraud. (Complaint, ¶¶ 82-89) They did so through filings submitted by their attorneys, executives, and employees, all of whom indubitably had obligations of candor and good faith when prosecuting the patent on behalf of their corporate principals. (*See, e.g.*, *id.*, ¶¶ 69-71, 82-89) Defendants cannot escape liability by hiding behind their agents. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 & n.1 (Fed. Cir. 1995); *Competitive Techs. v. Fujitsu Ltd.*, 286 F. Supp. 2d 1118, 1149 (N.D. Cal. 2003) (patent assignee "may be held liable [for fraud] on the basis that [the exclusive licensee of the patent] was acting as its agent in the licensing negotiations").

More generally, outside of patent infringement actions, principals are liable for the fraud committed by their agents. *See Am. Soc'y of Mech. Eng'rs v. Hydrolevel Corp.*, 456 U.S. 556, 566 (1982). Business entities such as Defendants may only act through natural persons. The law therefore charges them with the combined knowledge that comes to them through their officers, employees, or agents. *See, e.g.*, *United States* ex rel. *Polukoff v. St. Mark's Hosp.*, 895 F.3d 730,

[13] Contrary to Defendants' argument, the FCA makes clear that intent may be pleaded generally, and the statute "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). In any event, the Complaint pleads specific intent though not required. For example, Mr. Auerbach is the founder, CEO, President, and Director of defendant Janssen Oncology. A reasonable inference based on Mr. Auerbach's position is that he knew full well the FDA approval status of Zytiga's principal competitor; that Zytiga was protected by a blocking patent; and that the reasons for Zytiga's supposed commercial success had nothing to do with what Defendants claimed.

745 n.9 (10th Cir. 2018) ("It is well established that a corporation is chargeable with the knowledge of its agents and employees acting within the scope of their authority.") (quotation marks omitted); *Frank v. Dana Corp.*, 646 F.3d 954, 963 (6th Cir. 2011).

IV. BTG Participated in the Fraud

As this Court previously found, and as the Complaint alleges, BTG is a co-owner of the'438 patent. (Complaint, ¶ 91; *BTG*, 352 F. Supp. 3d at 358). BTG argues that the '438 patent was prosecuted by J&J, and BTG is not liable for fraud in connection with the prosecution of the patent. BTG, however, ignores that the fraud alleged in the Complaint is not limited to obtaining the patents. The fraudulent scheme also encompasses asserting the patents against generic competitors to unlawfully inflate the prices the government paid for the drugs, and also to take away the government's ability to choose less-expensive generics that would be sold by Defendants' competitors. (*See* Complaint, ¶¶ 92-132) BTG was involved in all of that subsequent misconduct and therefore is jointly and severally liable even if it was not present when the Patent Office was first defrauded. *See, e.g.*, *Mortgs., Inc. v. United States Dist. Court*, 934 F.2d 209, 212 (9th Cir. 1991); *United States v. Bourseau*, 2006 WL 2961105, at *13 (S.D. Cal. Sept. 29, 2006).

Analogizing to inequitable conduct cases (from which this case is *a fortiori*), BTG would be liable even if it had no role in the fraud because, in cases involving allegations of inequitable conduct, the consequences of patent fraud do not disappear even when a patent is transferred to an innocent third-party. Instead, the Federal Circuit has confirmed that a patent-plaintiff is liable for asserting patents acquired from a third party that committed inequitable conduct—even though there was no direct evidence that the plaintiff previously knew about the misconduct—because the plaintiff "should have known" that the patents "were unenforceable." *See In re Rembrandt Techs. LP Patent Litig.*, 899 F.3d 1254, 1272 (Fed. Cir. 2018).

Put another way: Fraud on the Patent Office cannot be laundered out by transferring the interest in the fraudulent patents to a third party such as BTG. As a current owner of the '438 patent, BTG is liable for how the patents were obtained and then used to exploit the government.

V. Defendants' Public Disclosure Argument Lacks Merit

Defendants' principal argument for dismissal has nothing to do with their own misconduct; instead, Defendants argue that even if they committed fraud, Relator's suit must be dismissed because the allegations or transactions alleged in the Complaint were publicly disclosed. The FCA's public disclosure provision provides for the dismissal of an action if "substantially the same allegations or transactions as alleged in the action" were publicly disclosed in (i) a "Federal criminal, civil, or administrative hearing in which the Government or its agent is a party"; (ii) a "congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation"; or (iii) "news media." 31 U.S.C. § 3730(e)(4)(A). A relator is an "original source" if he has "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," and "has voluntarily provided the information to the Government before filing an action under this section." *Id*. § 3730(e)(4)(B).

In 2010, Congress "overhauled" and "radically changed" the FCA to "lower the bar for relators." *United States* ex rel. *Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 298–99 (3d Cir. 2016). Congress narrowed the public disclosure bar in two important ways. First, the bar previously was triggered by disclosures made in any criminal, civil, or administrative hearing or proceeding[14]—and not only in federal hearings or proceedings in which the government was a party. Congress narrowed the bar in 2010 to apply only to information disclosed in proceedings in which the federal government participated as a party and therefore reasonably

[14] Defendants acknowledge a "hearing" under § 3730(e)(4)(A)(i) is synonymous with a "proceeding." (MTD 11)

likely to know about the fraud. Second, Congress liberalized the definition of an "original source." Previously, the FCA required a relator to have "direct" or firsthand knowledge of the fraud. Congress removed that requirement in 2010 to facilitate lawsuits by knowledgeable outsiders such as Mr. Silbersher.

There are three fatal defects with Defendants' argument. First, the critical allegations of fraud have never been disclosed anywhere. Second, any relevant disclosures were in a forum not covered by the statute. Third, Relator qualifies as an "original source" of the information.

A. Relator's Allegations of Fraud Have Never Been Publicly Disclosed

Defendants do not argue that all the allegations of fraud were publicly disclosed. Instead, they claim that only some of the same arguments about the invalidity of the '438 patent were disclosed in IPRs. (MTD 13-17) Even if that were true, it would not entitle Defendants to dismissal on this affirmative defense. The fraud in this case is bigger than the mere invalidity of the '438 patent. That was the first step, but the fraud also involved listing in the Orange Book, pricing negotiations, the availability of generic competitors, and payments from the government.

Moreover, the IPRs did not disclose the *fraud* alleged in this suit. Other than generally refuting Defendants' analysis of the nexus between the '438 patent's claimed invention and Zytiga's market share performance, the IPRs do not allege fraud. This is not surprising because the PTAB does not have jurisdiction to invalidate a patent based on fraud. 35 U.S.C. § 311(b).

None of the purported public disclosures relied upon by Defendants disclose one of the most important allegation of fraud in the Complaint: Defendants failed to disclose that Zytiga's principal competitor for chemo-naïve patients (Xtandi) had not obtained FDA approval during the relevant time period for which Defendants made a misleading market share comparison. (*Compare,* Complaint, ¶ 84(a)-(d) with RJN Exs. D-F) Defendants assert that the IPR petitions vaguely challenged the "data as 'deficient' and contended that Zytiga's commercial success was, in

fact, less robust." (MTD 16, citing RJN Exs. D & E). But this is not the fraud Relator asserts. The Complaint specifically alleges that Defendants told the Patent Office that Zytiga gained market share against Xtandi, thereby misrepresenting and omitting that the reason for the commercial success was because Xtandi had not received FDA approval. (Complaint, ¶¶ 82-84) This allegation is found nowhere in any of Defendants' alleged public disclosures.

Defendants attempt to defend their fraud by stating that "the June 4 submission included an FDA press release that announced Xtandi's FDA approval date for the *chemo-refractory* market," and "J&J could hardly be expected to disclose Xtandi's approval date for the chemo-naïve market, as that approval had not yet occurred." (MTD 17-18) This makes no sense. The Complaint does not fault Defendants for failing to disclose the *precise future* date of FDA approval of Xtandi in the chemo naïve market; Defendants are culpable for failing to disclose that such approval had *not yet occurred*. (Complaint, ¶¶ 82-84) A jury can easily find Defendants' June 4, 2013 submission to be misleading based on this material omission.[15]

Defendants also say that a few reasons for Zytiga's commercial success unrelated to the purportedly inventive claims of the '438 Patent (such as the drug resistance in patients, the median survival rates, and the anti-cancer properties of abiraterone acetate), as opposed to co-administration with prednisone, were disclosed in J&J's June 2013 submission. (MTD 18-20) But the June 2013 submission, disclosed only on PAIR, does not constitute a public disclosure. Further, even if the patent filings mentioned these facts (including a disclosure of the '213 patent with respect to the efficacy of 17α-hydroxylase/C17,20-lyase inhibitors in treating cancer) (RJN, Ex. I, at 7, ¶ [0035]), they were not raised in connection with Defendants' claims of commercial

[15] Indeed, this Court noted in *BTG*, 352 F. Supp. 3d at 388, that "Xtandi was approved in 2012" without noting the critical distinction between Xtandi's 2012 approval in the chemo-refractory market and its subsequent 2014 approval for the chemo-naïve market. This is not surprising, because this critical evidence of fraud was never raised by the parties in the patent infringement action before this Court; in the IPRs; or anywhere else.

success. Defendants cited them for different purposes, and they do not constitute adequate disclosure to the Patent Office as required by Rule 1.56. For example, the Complaint does not allege fraud based upon Defendants' failure to disclose the '213 patent during prosecution of the '438 patent application. Rather, Defendants told the Patent Office that Zytiga's commercial success was attributable to the alleged invention in the '438 patent—coadministering the drug with prednisone—but failed to apprise the Patent Office that a blocking patent was largely responsible for that success. (*See* Complaint, ¶ 87(e))

Finally, Defendants argue that facts relating to Zytiga's commercial success that Defendants failed to disclose to the Patent Office were disclosed in various scientific articles and elsewhere. (MTD 19-20, *citing*, *e.g.*, RJN Exs. I, O, G, V, W, X, Y, Z, AA, KK) Defendants' argument suffers from a critical logical flaw. Assuming, for the sake of argument, that the real reasons for Zytiga's commercial success (unrelated to the claimed invention in the '438 patent) were publicly disclosed, this does not mean the essential elements of Relator's fraud allegations were publicly disclosed. The Complaint alleges Defendants should have *but did not* disclose to the Patent Office such reasons for Zytiga's apparent commercial success. (Complaint, ¶¶ 80-89) That is the crux of Relator's fraud allegations, and Defendants' *failure to disclose them* appear nowhere in the documents Defendants cite. Those facts are *absent* in the patent prosecution filings, but the absence of the references is not the same as the disclosure of their omission.

B. The Relevant Transactions Were Not Disclosed in an Enumerated Forum

Even if the allegations or transactions in the Complaint had been publicly disclosed, the disclosure would not matter because to trigger the dismissal provision, transactions must be disclosed in a forum enumerated in the statute, *i.e.*, a hearing in which the government is a party, a federal report, or the news media. 31 U.S.C. § 3730(e)(4)(A). Defendants' key argument is that if the government had reviewed the materials submitted during the IPRs, and to a lesser extent the

patent prosecutions, it could have spotted the fraud alleged in the Complaint. (See MTD 10-13) Defendants' argument is unpersuasive because neither IPRs nor patent prosecutions are qualifying public *fora* enumerated in the FCA's public disclosure bar. They are administrative proceedings in which the government is not "a party." *See* 31 U.S.C. § 3730(e)(4)(A)(i). Accordingly, they are exactly the sort of proceeding Congress expressly carved out of the statute in 2010.

In ordinary parlance, a "party" means one of the protagonists in an adversarial dispute. In this case, for example, Relator is a party, and Defendants are parties. But even though the Court is involved, it is not a party. The government's relationship to IPRs is similar: IPRs happen when a private party files a petition challenging the validity of another party's patent. The government is involved because administrative patent judges at the PTAB adjudicate the dispute. *See* 35 U.S.C. § 6(a). They decide whether there is enough in the petition to institute a proceeding (similar to adjudicating a motion to dismiss), and they ultimately adjudicate the claim. But in such proceedings, the government is not a party, as that term ordinarily is used.

Indeed, the government *cannot* be a party to an IPR (unless it is sued as a patent owner). Recently, the Supreme Court confirmed that the government is not a "person" who can initiate or pursue an IPR claim against a patentee. *See Return Mail, Inc. v. United States Postal Serv.*, 139 S. Ct. 1853, 1866 (2019). Prior to that, the Court explained the statute authorizing IPRs provides that "*a party* may seek inter partes review by filing 'a petition to institute an inter partes review.' § 311(a). This language doesn't authorize the Director [of the Patent Office] to start proceedings on his own initiative . . ." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) (emphasis added).

Defendants argue that IPRs are administrative proceedings in which the government is a party because IPRs are like agency enforcement actions. (MTD 11) In support, they note that the PTAB may continue with an IPR to decision even if the petitioner or the application stops participating; and the Patent Office may "intervene" in any appeal from the PTAB's decision to

defend the decision. (*Id.* 11-12) As an initial matter, Defendants do not assert that the contingencies they describe arose in this case. Thus, even if Defendants are right that the government may *become* a party in *some* IPRs, that did not happen here.

More fundamentally, Defendants' arguments are legally insufficient to overcome the Supreme Court's holdings establishing that the government may not itself commence IPRs. Indeed, Defendants do not even mention *Return Mail* and *SAS Institute*. Defendants instead cite *Regents of the Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1339 (Fed. Cir. 2019) and *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1329 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 1547 (2019).[16] (MTD 11) These citations are unpersuasive because they are about an entirely different matter: whether tribal or state sovereign immunity defeats the PTAB's jurisdiction. This has nothing to do with whether the government is a "party" to an IPR under the FCA.

Defendants also argue that the *purpose* of an IPR is to reexamine an earlier agency decision and protect the public interest. (MTD 11 & n.11) Again, that is true—but that does not mean the government is a "party" to IPRs, any more than a judge's paramount role in upholding

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[16] *Saint Regis* involved Allergan's attempt to extent its patent monopoly for Restasis®, a dry eye drug, through several follow-on patents. After these patents were invalidated, several antitrust suits were filed claiming that private payors for Restasis were overcharged hundreds of millions of dollars because Allergan asserted the invalid patents to exclude generic competitors, inflating the drug's price substantially. *See In re Restasis Antitrust Litig.*, No. 18-md-02819 (E.D.N.Y.).

Defendants tell the Court that Relator is also litigating "identical claims packaged as antitrust suits" in the *In re Restasis* class actions, presumably because Defendants believe Relator's involvement with them demonstrates recurring "parasitic" behavior. (MTD 1, n.2) The opposite is true. *Restasis;* this case; the subsequent antitrust class actions pending before the Court; and the other *qui tam* actions involving Allergan and Valeant to which Defendants cite—they all demonstrate the problem of high drug prices caused by fraudulently-obtained patents.

These cases demonstrate why *qui tam* actions such as this one are vital to protecting scarce health care funds. The misconduct of some pharmaceutical companies such as Defendants are what rightfully should be called "parasitic"—because such misconduct costs taxpayers billions of dollars. The "parasitic" canard, on the other hand, does not fit Relator, who is trying to halt these massive predation on healthcare funds that the government did even not know about.

the public's interest in the administration of justice renders the government a party in all civil actions. At a minimum, it is hard to see how the Court could accept Defendants' argument without holding that essentially *every* administrative proceeding is covered by the public disclosure bar, because any time anybody seeks an agency decision, the agency acts in the public interest. But Congress plainly carved out administrative proceedings in which the government is not a party—making it clear that it could not have intended such a sweeping result.

With respect to the supposed disclosures in the patent prosecution filings, Defendants assiduously avoid any consideration of whether a patent prosecution constitutes a "hearing in which the Government or its agent is a party." 31 U.S.C. § 3730(e)(4)(A)(i).[17] This is because patent prosecution is an *ex parte* administrative proceeding in which the government is manifestly not a party. *See, e.g.*, *ICU Med., Inc. v. B. Braun Med. Inc.*, 2005 WL 588341, at *13 (N.D. Cal. Mar.14, 2005). Thus, these proceedings also fall squarely within the category of hearings that Congress sought to carve out of the public disclosure bar in 2010.

Defendants attempt to circumvent Congress's amendment by arguing that even though facts disclosed in the proceedings themselves could not qualify as public disclosures, the documents submitted in the IPRs and the patent prosecution are "Federal reports" or "news media." (*See* MTD 12-14, 19-20) These arguments are also unpersuasive.

First and foremost, Defendants' position cannot be reconciled with the statutory text. In statutory interpretation, the "specific governs the general," *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (quotation marks omitted), and courts are "obliged to give effect, if possible, to every word Congress used," *Nat'l Ass'n of Mfrs. v. Dep't of Defense*, 138 S. Ct. 617, 632 (2018) (quotation marks omitted). In 2010, Congress specifically added the

[17] For purposes of § 3730(e)(4)(A)(i), a "hearing" is synonymous with "proceeding." *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1244 (9th Cir. 2000).

phrase "in which the Government or its agent is a party" to the "hearings" subsection of the public disclosure provision, making it clear that it wished to "exclude from the public disclosure bar information disclosed at hearings in cases in which the Government is *not* a party." *Integra*, 2019 WL 3282619, at *11. Defendants' argument here would nullify that new limitation for every proceeding with a public docket, including all private federal litigation (available on PACER). This would "swallow limitations that Congress specifically placed on the scope of the public disclosure bar," and "run contrary to the purposes underlying the public disclosure bar, and indeed the FCA itself." *Integra*, 2019 WL 3282619, at *11-12.

Second, Defendants' argument is inconsistent with controlling precedent. Defendants have not cited a single case—controlling or otherwise—holding that documents available through PAIR or the PTAB filing system trigger the public disclosure bar under the current version of the statute. Nor do Defendants cite a single case holding that IPR filings available on the PTAB electronic filing system (similar to PACER, called "PTAB E2E") would qualify as a public disclosure. Instead, Defendants' argument contradicts the Supreme Court's holding in *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401 (2011). *Schindler* emphasized using the "ordinary meaning" of the terms in the public disclosure bar. 563 U.S. at 410. Nobody would say that a patent submission, prepared by a private inventor and submitted to the Patent Office, constitutes a "Federal report" or "news media." Moreover, neither PAIR, PACER, nor PTAB E2E is anything like the written FOIA response analyzed in *Schindler*. Both PAIR and PTAB E2E post docket entries online automatically; and they do not require federal employees to publish the information—let alone make a "determination" about what responsive information to include.

Third, Defendants' "news media" argument has been rejected by a recent, well-reasoned decision. *See Integra*, 2019 WL 3282619, at *11. The *Integra* court noted that cases treating broad swaths of the Internet as "news media" have ignored the Supreme Court's guidance in *Schindler* to

construe terms in the public disclosure bar consistently with their ordinary meaning. *Id.*, at *12. No one would call PAIR or PTAB E2E "news media" in ordinary parlance: The term "generally carries with it a connotation of editorial independence, or at least some separation, between the original source of information and the medium that conveys it." *Id.* at *14.

Defendants have pointed to literally no case holding that IPR filings or patent prosecution submissions constitute either "Federal reports" or "news media." To accept Defendants' interpretation, the Court would have to make new law expanding the scope of these terms so as to nullify the 2010 amendments to the FCA.

Unable to persuasively argue that the IPRs themselves were qualifying public disclosures, Defendants say that the *existence* of the IPRs were reported in news articles and J&J's SEC filings. (MTD 14) But those articles and SEC filings simply mentioned that the IPRs had been *commenced* (this case was filed before any of the IPRs were decided). The proffered articles contain no disclosure about any of the fraud alleged in the Complaint. It is no wonder Defendants do not bother to identify anything in them that would constitute a relevant disclosure.[18]

C. In the Alternative, Relator Is an Original Source.

Even if there has been a public disclosure in an enumerated forum of all the material elements constituting fraud—which did not occur—Relator may still pursue his claims if he is an "original source" possessing "knowledge that is independent of and materially adds to" the

[18] At most, the news articles and SEC reports merely disclose the *existence* of the IPRs, without describing their contents or linking to them. They lack the requisite level of specific, granular detail sufficient to alert the government of fraud. *Cf. United States v. Omnicare, Inc.*, 903 F.3d 78, 89, *citing United States* ex rel. *Mateski v. Raytheon Co.*, 816 F.3d 565, 577 (9th Cir. 2016).

Defendants' reliance on *U.S.* ex rel. *Proctor v. Safeway, Inc.*, No. 11-cv-3406, 2016 WL 7017231, at *12 (C.D. Ill. Dec. 1, 2016) is misplaced. *Proctor* is of no persuasive value because it does not explain what materials regarding the lawsuit, or which material in the court file, constituted public disclosure. *Proctor* also denied the motion to dismiss because there was no public disclosure.

publicly disclosed allegations or transactions.[19] *See* 31 U.S.C. § 3730(e)(4)(B). The question of whether a Relator's knowledge "materially adds to" publicly disclosed allegations or transactions is a fact issue, and it should not be resolved on a Rule 12 motion. *Cf. United States* ex rel. *Freedom Unlimited, Inc. v. City of Pittsburgh*, 728 F. App'x 101, 104-05 (3d Cir. 2018).

Defendants' assertion that Relator "repackaged" material that was publicly filed rings hollow. (MTD 1, 21-23) For example, through his particular knowledge and expertise, Relator uncovered Defendants' misleading and nonpublic omission of material facts concerning FDA approval dates for Xtandi when comparing that drug's market share with Zytiga's. (Complaint, ¶ 84(a)-(d)) This is a critical allegation of fraud alleged in the Complaint, and no document that Defendants cite disclosed it.

CONCLUSION

The Motion to Dismiss should be denied in its entirety.[20] In the alternative, the Court should permit Relator to amend his pleadings should there be any deficiency.

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[19] The Complaint alleges that Relator provided the information alleged in the Complaint to the government "before filing this action." (Complaint, ¶ 17) In a typographical error, the Complaint erroneously identified this date as June 5, 2019 (which would not be "before" this action was commenced). The correct date is June 20, 2017.

[20] Defendants, as an afterthought, assert that Relator has failed to plead causes of action under the Plaintiff States' false claims statutes in footnote 43 at the end of their brief. Defendants' unsupported and unexplained assertion concerning New Mexico should be rejected out of hand.

The Texas Attorney General has requested Relator to inform the Court that liability for the Texas causes of action do not require the presentment of a false claim, and most do not require proof of materiality. Tex. Hum. Res. Code §§ 36.002(1)-(13). Therefore, Defendant's arguments do not apply to Texas.

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